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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,232	02/15/2001	Nicholas L. Abbott	032026:0502	2504

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EXAMINER

TRAN, MY CHAUT

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 04/05/2002

J

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/784,232	ABBOTT ET AL.
	Examiner	Art Unit
	My-Chau T. Tran	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 23 January 2002.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-63 is/are pending in the application.  
 4a) Of the above claim(s) 19-63 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-18 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 15 February 2001 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a)  The translation of the foreign language provisional application has been received.  
 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)                            4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 & 8.                    6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-18, in Paper No. 7 is acknowledged. The traversal is on the ground(s) that the search and examination would not be burdensome if Group II-IV, claims 19-63, are rejoined with Group I because of overlapping features. This is not found persuasive because although there are overlapping features among these inventions, Group I-IV, the search requirement is *not* coextensive that a search for one invention would *not encompass* the limitations of the other inventions thus resulting in divergent of the search evaluations. The search and examination of all four inventions would be burdensome. Therefore, Group II-IV is not rejoined with Group I.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Drawings***

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: ref. # 21 of fig. 3. A proposed drawing correction, corrected drawings, or amendment to the specification to add the

reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: ref. # 33 of fig. 3. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "20" (pg. 13, line 5) and "21" (pg. 16, line 28-29) have both been used to designate a substrate. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "33" has been used to designate both a layer (pg. 17, line 25-26) and a film (pg. 17, line 31). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Objections***

7. Claim 4 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 4 is dependent on itself. In furthering the process of compact prosecution, the examiner will presumed that claim 4 is dependent on claim 3.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that there is no method steps in the detection of the pathogen. It also lacks contacting and correlation steps in the detection of the pathogen.

It is unclear in claim 1 the relationship that the liquid crystal has with the substrate. It is a bi-layer that is attaches to the substrate or a covering for the substrate.

It is unclear what the method steps are for the detection of the pathogen of claims 3-7 since it is just claiming the type of substrate.

Claims 10 and 15 are also claiming the size of the depression but are unclear on how this correlates with the method step of detecting the pathogen. Since such a claim relates to the device and not the method of detection.

It is unclear what the method steps are for the detection of the pathogen of claims 11-13 since it is just claiming the size of the grooves.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

(f) he did not himself invent the subject matter sought to be patented.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-7, 14 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Abbott et al. (US Patent 6,284,197 B1).

Abbott et al. anticipated the claimed invention by teaching a method for detection of an analyte. The method steps include providing a substrate (a first substrate), a binding agent (a recognition moiety), and the detection of the analyte is due to the interaction of the analyte with the binding agent on the substrate. This binding causes a visual distortion of the liquid crystal

(mesogens) enabling the detection of the analyte (col. 14, line 16-43). The analyte is a biomolecule (pathogen) (col. 26, line 21-23; col. 29, line 11-15). The detection region (substrate) is coated with gold (gold film) and treated with disulfide (col. 22, line 4-39). The substrate is formed from a polymer, preferably polydimethylsiloxane (col. 15, line 66-67 and continue to col. 16, line 1-14). The binding agent is a peptide, antibody, or protein (col. 26, line 30-36; col. 28, line 53-67). The binding agents are located in the depression of the detection region (col. 40, line 42-44).

12. Claims 1-6, and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Abbott et al. (US Patent 6,277,489 B1).

Abbott et al. anticipated the claimed invention by teaching a method for detection of an analyte. The method steps include providing a substrate (a first substrate), a binding agent (a recognition moiety), and the detection of the analyte is due to the interaction of the analyte with the binding agent on the substrate. This binding causes a visual distortion of the liquid crystal (mesogens) enabling the detection of the analyte (col. 14, line 16-43). The analyte is a biomolecule (pathogen) (col. 51, line 27-31). The detection region (substrate) is coated with gold (gold film) and treated with disulfide (col. 11, line 34-37 and 51-55). The substrate is formed from a polymer (col. 11, line 8-18). The binding agent is a peptide or antibody (col. 19, line 56-59; col. 26, line 18-25).

13. Claims 1-7 and 14 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The inventorship of the US Patent 6,284,197 B1 includes

Vinay K. Gupta, Timothy B. Dubrovsky, and Rahul Shah, which are not listed in the instant application. The assignee of this patent is The Regents of the University of California, which is different from the instant application, Wisconsin Alumni Research Foundation.

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being obvious over Abbott et al. (US Patent 6,284,197 B1) in view of Leavitt et al. (US Patent 5,712,103).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The method of Abbott et al. is disclosed above.

The method of Abbott et al. differs from the claimed invention in failing to teach coating the substrate with bovine serum albumin.

Leavitt et al. teaches a method step where an assay involves an antigen or antibody (immunoglobulin) immobilized on a substrate and to minimize the non-specific binding by coating the substrate with bovine serum albumin (col. 10, line 2-12). Leavitt teaches that it is well known in the art that proteinaceous materials such as bovine serum albumin, are commonly used to coat solid substrate to reduce non-specific binding.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Abbott et al. by including a method step to minimize the non-specific binding by coating the substrate with bovine serum albumin as taught by Leavitt et al. Leavitt teaches that it is well known and advantageous to use bovine serum albumin to coat a solid substrate to reduce non-specific binding.

18. Claims 10-13 and 15 are rejected under 35 U.S.C. 103(a) as being obvious over Abbott et al. (US Patent 6,284,197 B1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in

the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The method of Abbott et al. is disclosed above.

The method of Abbott et al. differs from the claimed invention in failing to specifically teach the dimensions of the depressions (well). However, Abbott teaches that the size and complexity of the pattern on the substrate is limited only by the resolution of the technique utilized and the purpose for which the pattern is intended, which is to confine the analyte of interest (col. 17, line 7-27). Abbott teaches patterning the substrate such that features of about 1  $\mu\text{m}$  - 200 nm are possible.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the dimensions of the wells on the surface of substrate, as taught by Abbott, to meet the needs and to satisfy the purpose for which the pattern is intended, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

19. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott et al. (US Patent 6,284,197 B1) in view of Leavitt et al. (US Patent 5,712,103) as applied to claims 8-9 above, and further in view of Chagnon et al. (US Patent 4,628,037).

The method of Abbott et al. as modify by Leavitt et al. is disclosed above.

The method of Abbott et al. as modify by Leavitt et al. differs from the claimed invention in failing to specifically include the use of magnetic beads.

Chagnon et al. teaches a binding assay method that involves using magnetic particles (beads) to measure the amount of analyte (col. 9, line 58-64). This method would permit a homogeneous reaction conditions that promote optimal binding kinetics and minimally alter analyte-adsorbent equilibrium (col. 2, line 51-55).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Abbott et al. as modify by Leavitt et al. by including a method step that involve using magnetic particles (beads) to measure the amount of analyte as taught by Chagnon et al. for the advantage of permitting a homogeneous reaction conditions that promote optimal binding kinetics and minimally alter analyte-adsorbent equilibrium.

### ***Double Patenting***

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 1 and 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 5-7 of U.S. Patent No. 6,284,197 (Abbott et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to those of ordinary skills in the art to recognize that the claims of the patent (Abbott et al.) would encompass the claimed invention.

The application and Abbott both teach a method for detection of an analyte. The method steps include providing a substrate (a substrate), and a binding agent (a recognition moiety) on the substrate. Detection of the analyte is due to the interaction of the analyte with the binding agent, which causes a visual distortion of the liquid crystal, enabling the detection of the analyte. The analyte is a biomolecule (pathogen). The binding agent is a peptide, antibody or biotin.

### *Conclusion*

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following prior art teaches the state of the art of liquid crystal: Woolverton et al. (US Patent 6,171,802 B1), and Meathrel (US Patent 4,597,942).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct  
April 3, 2002

*BAO-THUY L. NGUYEN*  
BAO-THUY L. NGUYEN  
PRIMARY EXAMINER  
*4/4/02*